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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/937,386   | 01/08/2002  | Meir Shinitzky       | SHINITZKY=4         | 5565             |
| 1444   | 7590        | 04/05/2004           | EXAMINER            |                  |
| BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      | SHIAO, REI TSANG    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1626                |                  |

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/937,386

Applicant(s)

SHINITZKY, MEIR

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 1/12, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37, 45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37, 45 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This application claims benefit of the foreign application: Israel 129179 with a filing date March 25, 1999.
2. Applicant's amendment of claims 1, 13, 17, 22, 25-27, 31-32, 36-37, and 45-46, and cancellation of claims of 38-44 in Paper No. 0104, dated January 12, 2004, is acknowledged. Claims 1- 37 and 45-46 are pending in the application.

### ***Responses to Amendment***

3. The rejection of claims 17, 25, 36, and 37 under 35 U.S.C. 112, first paragraph, has been overcome in Paper No. 0104, dated January 12, 2004. Since no name diseases have been claimed in the claims 31-32, therefore, the rejection of claims 31-32 under 35 U.S.C. 112, first paragraph, is maintained. The rejection of claims 1-2, 5, 11-23, and 45 under 35 U.S.C. 102(b) has been overcome in Paper No. 0104, dated January 12, 2004. Since claim 44 has been cancelled, therefore, the rejection of claim 44 under 35 U.S.C. 102(b) is obviated.

### ***Responses to Arguments***

4. Applicant's argument regarding the rejection of claims 1-2, 5, 22-23, and 45 under 35 U.S.C. 103(a) in Paper No. 0104, dated January 12, 2004, have been fully considered and they are persuasive. Since Watanabe et al. 6,346,594 disclose an intermediate "2-methoxy-2-oxo-1, 3,2-dioxzphospholane", which does not disclose compositions/methods of use treating cancer, therefore, the rejection of claims 1-2, 5,

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22-23, and 45, therefore, the rejection of claims 1-2, 5, 22-23, and 45 under 35 U.S.C. 103(a) has been withdrawn. Since claim 44 has been cancelled, therefore, the rejection of claim 44 under 35 U.S.C. 103(a) is obviated.

5. Applicant's arguments with respect to claims 1-37 and 45-46 have been considered but are moot in view of the new grounds of rejection.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 37 and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by (1) Chabrier et al. FR 2193023, see CAS: 82:56871; (2) Yasuda et al. Publication, Macromolecules, 1981, 14(2): 458-60, see CAS: 94: 175602; (3) Quin et al. publication, Heteroatom Chemistry, 1991, 2(1): 99-110, see CAS: 115: 29459; (4) Eto et al. publication, Nippon Kagaku Kaishi, 1981, 5: 705-11, see CAS: 95: 75384; (5) Yasuda et al. publication, Macromolecules, 1982, 15(5): 1231-7, CAS: 97: 163550; (6) Kobayashi et al. JP 09025235, see CAS :126 :220705.

Applicants claim compounds/composition of formula (I), and the compounds are found in the pages of 6-10 of instant application.

Chabrier disclose a compound 1,3,2-Dioxaphospholane, 2-(2-methoxyphenoxy)-, 2-oxide, which clearly anticipated the compound of formula (I), wherein the variable Y is  $-(CH_2)_m-$ , and m is 0, the variable R represents substituted aryl, the variable X represents hydrogen, see RN: 39683-72-2 of CAS: 82:56871.

Yasuda et al. disclose a compound 1,3,2-Dioxaphospholane, 2-(1,1-dimethylethoxy)-4-methyl-, 2-oxide, which clearly anticipated the compound of formula (I), wherein the variable Y is  $-(CH_2)_m-$ , and m is 0, the variable R represents alkyl, the variable X represents alkyl, see RN: 76819-62-0 of CAS:94:175602.

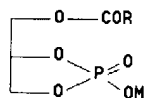
Quin et al. disclose a compound 1,3,2-Dioxaphospholane, 2-ethoxy-4-methyl-, 2-oxide, trans-, which clearly anticipated the compound of formula (I), wherein the variable Y is  $-(CH_2)_m-$ , and m is 0, the variable R represents alkyl, the variable X represents alkyl, see RN:60787-21-5 of CAS:115:29459.

Eto et al. disclose a compound 1,3,2-Dioxaphospholane, 2-ethoxy-4-ethyl-, 2-oxide, which clearly anticipated the compound of formula (I), wherein the variable Y is  $-(CH_2)_m-$ , and m is 0, the variable R represents alkyl, the variable X represents alkyl, see RN:78447-88-8 of CAS: 95:75384.

Yasuda et al. disclose a compound 1,3,2-Dioxaphospholane, 2-methoxy-, 2-oxide, which clearly anticipated the compound of formula (I), wherein the variable Y is  $-(CH_2)_m-$ , and m is 0, the variable R represents alkyl, the variable X represents hydrogen, see RN:82940-88-3 of CAS:97:163550.

Kobayashi et al. disclose compounds/composition of formula (I) as agents treating cancer,

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I

, wherein M is hydrogen or cation, and the variable R represents C<sub>2-30</sub> linear or branched alkyl, which clearly anticipated the compound of formula (I), wherein the variable Y is -(CH<sub>2</sub>)<sub>m</sub>-, and m is 0, the variable R represents hydrogen or cation (i.e., Na), the variable X represents CH<sub>2</sub>Oacyl, see CAS:126:220705.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

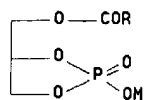
Claims 1- 37 and 45-46 are rejected under 35 U.S.C. 103(a) as obvious over Kobayashi et al. JP 09025235, see CAS: 126:220705.

Applicants claim compounds/composition of formula (I), and the compounds are found in the pages of 6-10 of instant application.

### **Determination of the scope and content of the prior art (MPEP §2141.01)**

Kobayashi et al. disclose compounds/composition of formula (I) as agents treating cancer,

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, wherein M is hydrogen or cation (i.e., Na), and the variable R represents C<sub>2-30</sub> linear or branched alkyl, which clearly anticipated the compound of formula (I), wherein the variable Y is  $-(CH_2)_m-$ , and m is 0, the variable R represents hydrogen or cation (i.e., Na), the variable X represents CH<sub>2</sub>Oacyl, see CAS:126:220705.

**Determination of the difference between the prior art and the claims (MPEP §2141.02)**

The difference between the instant claim and Kobayashi et al. is that the variable R of instant compounds represents alkyl, while Kobayashi et al. represents hydrogen or cation (i.e., Na).

**Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)**

One having ordinary skill in the art would find the instant claims prima facie obvious **because** one would be motivated to employ the compounds of Kobayashi et al. to obtain an instant compound of formula (I), wherein the variable Y is  $-(CH_2)_m-$ , and m is 0, the variable R represents hydrogen or cation (i.e., Na), the variable X represents CH<sub>2</sub>Oacyl.

The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds would possess similar activity (i.e., treating cancer) to that which is claimed in the reference.

### ***Objection***

8. Claim 17 is objected to for being substantial duplicates of the claim 1 from which they depend. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k).

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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